PATENT

UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	Tracee E.J. Eidenschink	Confirmation No.:	1707
Serial No.:	10/034,586	Examiner:	Vi X. Nguyen
Filing Date:	December 27, 2001	Group Art Unit:	3734
Docket No.:	1001.1459101	Customer No.:	28075
For:	CATHETER HAVING AN IMPROVED TORQUE TRANSMITTING SHAFT		

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL CONFERENCE BRIEF

CERTIFICATE FOR ELECTRONIC TRANSMISSION:
The undersigned hereby certifies that this paper or papers, as described herein, are being electronically transmitted to the U.S. Patent and Trademark Office on this 18th day of JULY, 2008.

By _____
Thu H. Le-To

Dear Sir:

Appellants have carefully reviewed the Final Office Action of March 17, 2008 and the Advisory Action of June 12, 2008. Currently, claims 5-22 and 24-34 are pending in the application and have been twice rejected by the Examiner. Appellants hereby request a pre-appeal conference and file this pre-appeal conference brief concurrently with a Notice of Appeal. Favorable consideration of the claims is respectfully requested.

Appellants dispute the § 102 rejection over Foreman et al., U.S. Patent No. 6,569,192 (hereinafter "Foreman") and the § 103 rejection over Foreman as a sole reference because Foreman does not teach or suggest all the claim elements.

Foreman is directed to a stent delivery catheter where the balloon on which the stent is loaded has a number of protrusions that fit into the interstices of the stent to secure the stent in place during delivery. See, for example, the abstract and Figure 4. The protrusions are found only on the balloon at the distal end of the catheter and are used, Foreman teaches, to "prevent

relative motion between the stent and expandable member until the expandable member is inflated to implant the stent." Col. 2, ll. 62-64.

In contrast, the present invention claimed is, in general terms, directed to a catheter having a torque transmitting shaft, and methods of use. The shaft has protrusions that, when torque is applied to the catheter, contact and press against each other to provide improved torque transmission capabilities. In claim 1, for example, the most pertinent elements of this feature that are recited are "a raised pattern of generally noncontiguous elements disposed on the outer surface of the elongate shaft, the raised pattern further comprising a plurality of bearing points, wherein the bearing points are separated when the shaft is not being torqued and wherein at least two of the bearing points move toward one another when the shaft is torqued; and wherein the raised pattern improves the transmission of torque along the elongate shaft."Thus, to show anticipation or obviousness over Foreman, one needs to show that two of the protrusions on the balloon of Foreman move towards each other when the shaft is torque and that the raised pattern on the balloon improves the transmission of torque. Appellants do not believe this has been done nor that it can be done.There are three conditions of the balloon catheter of Foreman. The first is a delivery condition when the stent is loaded on the balloon for delivery but is not inflated. The second is when the balloon is inflated to install the stent. In this condition, the balloon is inflated with the stent on the balloon. The third condition is when the balloon is deflated after the stent has been installed.

There is nothing that appellants can find in Foreman to suggest that, when the shaft of Foreman is being torqued, two bearing points on the raised pattern more towards each other in any of these three conditions, nor is such a result inherent from the configuration disclosed by Foreman. As discussed above, the protrusions on the shaft of Foreman are on a stent delivery balloon and are used to secure the stent to the balloon during delivery. When the stent is on the balloon in the first and second conditions, the stent is disposed between the gaps of the protusions, as shown in Figure 4. Thus, during delivery and installation, it is plainly impossible to move bearing points towards each other by torquing the shaft.

The third case, of course, is when the stent is off the balloon after delivery. The construction of the catheter of Foreman includes two coaxial tubes connected at their proximal and distal ends. The inner tube defines a guide wire lumen and the space between the outer and

inner tubes defines the inflation lumen. The outer tube includes a balloon, which has a proximal skirt section, a working length and a distal skirt section. The protusions are found only on the working length of the balloon. The balloon is necessarily much more flexible than the tubes of the catheter because the balloon needs to change shape when inflation fluid is introduces into the inflation lumen while the tubes need to retain their shapes. This, appellants believe, is true for any angioplasty or stent-delivery catheter. The protrusions, if for no other reason than the added thickness, make the working length of the balloon less flexible than the proximal and distal skirts. Further, the balloon, as Foreman teaches and as is generally true, is much, much shorter than the overall length of the catheter and is at the distal end of the catheter. See col. 6, ll. 17-21.

Therefore, when torque is transmitted at the proximal end by the operator, the torque is transmitted through both the inner and the outer tubes down the length of the catheter. The radial displacement between the proximal and distal ends of the distal section of the catheter (where the balloon is) is relatively little because it is a relatively short section of the catheter. In this section, the inner tubular member is stiffer than the balloon and so transmits more of the torque. The proximal and distal balloons waists, being more flexible than the working length of the balloon take up most if not all of the radial displacement of the outer tube in this distal section. Because the balloon waists are more flexible than both inner and outer tubes and the working length of the catheter, they act as buffers that isolate the working length. It cannot therefore be reasonably speculated that the working length of the balloon twists during normal operation to move two of the protrusions closer together.

It may be possible to twist the catheter to the point where all the slack in the distal and proximal balloon skirts is taken up and the working length of the balloon starts to twist. However, such extensive twisting may twist the inner tube to the failure point. (One can take an ordinary table straw and twist it. When the straw is round, it can transmit a certain level of torque. However, once the straw collapses and folds in on itself, it can no longer transmit that same level of torque.) Thus because the two points on the raised pattern of Foreman may move towards each other only when the catheter has begun to fail because of overtorquing, one cannot say that the raised pattern on the balloon "improves the transmission of torque along the shaft" as recited in claim 1.

Further, there are a number of claims such as dependent claim 11, which contain the further limitation of "wherein the bearing points contact one another when the elongate shaft is torqued." There is nothing in Foreman to suggest that this condition can obtain from any level of non-destructive torquing. As discussed above, it may be possible to twist the catheter to such a point, but doing so may well damage the inner tube, and such a level of torque will decrease the torque transmission properties of the shaft rather than increase them.

As provided in MPEP 2111.01, "During examination, the claims must be interpreted as broadly as their terms reasonably allow. This means that the words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification." And "Plain meaning refers to the ordinary and customary meaning given to the term by those of ordinary skill in the art."

When, in order to attempt to meet the limitations of a claim, one may have to break the putatively anticipatory device, that device is outside the plain meaning of the claim language. Absent clear language to the contrary, when a claim recites a feature, that feature is understood to be present in the device by those of ordinary skill in the art without destructively manipulating the device.

In sum, there is nothing appellants can find in Foreman which suggest that the raised pattern on the balloon includes at least two shapes that move towards each other when the device is torqued or that this pattern of raised shaped is capable of improving the transmission of torque along the elongate shaft. As MPEP 2112 says (internal citations omitted), "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient."

Here, the Examiner can at most speculate that there is a possibility that the claim elements are present in Foreman. The Examiner has not shown that the missing description matter is *necessarily* present in Foreman and for the reasons discussed above, appellants submit that such a showing cannot be made. Foreman is directed to a balloon catheter to which a stent

may be removably secured. The present invention is directed to a catheter shaft that can improve the transmission of torque while retaining flexibility. The inventions are different and the language of the pending claims cannot be reasonably said to be anticipated by or obvious over Foreman.

For at least the reasons mentioned above, all of the pending claims are allowable over the cited prior art. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Tracee E.J. Eidenschink

By her Attorney,

Date: 7/18/08

David M. Crompton, Reg. No. 36,772
CROMPTON, SEAGER & TUFTE, LLC
1221 Nicollet Avenue, Suite 800
Minneapolis, MN 55403-2420
Telephone: (612) 677-9050
Facsimile: (612) 359-9349